

RESPONSE UNDER 37 C.F.R. § 1.116  
EXPEDITED PROCEDURE  
GROUP 1615  
PATENT APPLICATION

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q81147

Nobukazu ONISHI, et al.

Appln. No.: 10/826,303

Group Art Unit: 1615

Confirmation No.: 9815

Examiner: Susan T. TRAN

Filed: April 19, 2004

For: AGENT AND FOOD FOR INHIBITING IGE ANTIBODY

**RESPONSE UNDER 37 C.F.R. § 1.116**

**MAIL STOP AF**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated March 27, 2007, please consider the following remarks on the accompanying pages.

**REMARKS**

Claims 15, 17-19 and 21-22 are all the claims pending in the application; Claims 1-14, 16 and 20 have been previously canceled.

In the Amendment submitted December 22, 2006, Applicants noted that the Office Action Summary mailed September 25, 2006, indicated that none of the certified copies of the priority documents had been received by the Patent Office. Applicants requested that the Patent Office acknowledge in the next office communication, that a certified copy of the priority document had been received and was submitted in the parent application (U.S. Application No.

10/212,071), on November 12, 2002. However, in the Office Action mailed March 27, 2007, no such acknowledgement was made. Accordingly, Applicants respectfully request acknowledgement of the receipt of the certified copy in the next Office communication.

Referring to page 2 of the Office Action, Claims 15, 17-19, 21 and 22 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,939,239 to Matsuhashi et al ("Matsuhashi"), in view of U.S. Patent No. 5,462,761 to McGinley et al ("McGinley").

Applicants traverse the rejection for the following reasons.

As amended, Claim 15 is directed to a method for suppressing an allergy comprising administering a pharmacologically effective amount of an IgE antibody inhibitor containing glucomannan to a patient in need thereof, wherein the glucomannan is in the form of refined *konjak* flour, the glucomannan is easily soluble in water, the glucomannan is a pulverized product with an average particle diameter of 100  $\mu\text{m}$  or less, and the glucomannan has a dietary fiber content of 95% or more.

Matsuhashi is relied upon to teach a hyposensitization agent prepared by covalently attaching a saccharide, including glucomannan, to a cedar pollen allergen. (*See Abstract*). The saccharide is disclosed to have an average molecular weight in the range of 500-10,000,000 (col. 1, l. 54 to col. 2, l. 24).

On page 3 of the Office Action, it is acknowledged that Matsuhashi does not teach the average particle size of glucomannan. In this regard, McGinley is relied upon to disclose the use of a composition of matter comprising dry, water-dispersible particles of microcrystalline

cellulose (MCC) coprocessed with a glucomannan, and useful as bulking agents and fat substitutes, especially in water-based formulations such as foods. (*See Abstract*; col. 2, ll. 5-9; 20-23). McGinley further discloses that the glucomannan is derived from konjak, and may be native (crude) konjak flour, clarified konjak glucomannan, or cold-melt konjak (col. 2, ll. 62-65). McGinley teaches that the average particle size of the inventive dry MCC/glucomannan spheroidal particles is 0.1 to 100 microns (col. 2, ll. 57-61). It is asserted that it would have been obvious to modify the preparation taught by Matsuhashi using the particle taught by McGinley because McGinley allegedly discloses the use of glucomannan having a small particle size.

However, this analysis is not correct. First, Matsuhashi actually teaches away from using a saccharide that is not covalently bonded to an allergen. Specifically, Matsuhashi discloses a mixture (rather than a conjugate) of an allergen and a saccharide as a control sample in Tables 1-3, showing inferior results, compared to the use of allergen-saccharide conjugates.

Second, the use of glucomannan with an average particle diameter of 100  $\mu\text{m}$  or less, exhibits unexpected superior results versus the particle size disclosed in the prior art, which is not appreciated by Matsuhashi. In this regard, Applicants submit herewith an article by Nobukazu Onishi et al., entitled, "A New Immunomodulatory Function of Low-Viscous Konjac Glucomannan with a Small Particle Size: Its Oral Intake Suppresses Spontaneously Occurring Dermatitis in NC/Nga Mice" (herein after "Onishi et al."). Applicants refer the Examiner to Onishi et al. at page 260, left column, under "Results" and Table I in the right column. Therein, the physiochemical properties, including the average particle size of low-viscous konjac powders are disclosed. The particle sizes of the different varieties of konjac, as disclosed in Table 1, ranged from 105-315  $\mu\text{m}$ . When each of the particle sizes of konjac were tested, however, it was

“found that oral intake of low-viscous GM (S-P) with only small particle size restrained the progression of dermatitis, itching behavior, and plasma IgE evaluation in NC/Nga mice (fig. 1a, b, 3a, ...).” See Onishi et al. at page 263, left column, first paragraph under “Discussion”. Further, it is disclosed that, “These results implied that the suppressive effect of konjac GM on the development of AD-like dermatitis should depend upon the particle size rather than viscosity.” See Onishi et al. at page 263, left column, first paragraph under “Discussion”. Thus, the particle size, as recited in the claims of the present invention, results in unexpected superior results, not disclosed or suggested by either of the prior art references.

Further, independent Claims 15 and 19 have been amended to incorporate the feature of the glucomannan having a dietary fiber content of 95% or more. Neither Matsuhashi nor McGinley teach that the glucomannan utilized therein has a dietary fiber content of 95% or more, as recited in Claims 15 and 19.

In light of the deficiencies of the teachings of Matsuhashi and McGinley, the rejection of Claims 15 and 19 under 35 U.S.C. § 103(a) over Matsuhashi and McGinley, alone or in combination, is improper. Accordingly, withdrawal of the rejection is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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